

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

*DMB*

Display Date	<u>5-15-01</u>
Publication Date	<u>5-16-01</u>
Certifier	<u>TA3</u>

**New Animal Drugs For Use in Animal Feeds; Narasin, Nicarbazin, and Bambermycins**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

---

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Elanco Animal Health. The NADA provides for use of approved narasin/nicarbazin and bambermycins Type A medicated articles to make three-way combination Type C medicated feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency in broiler chickens.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 140-942 that provides for use of Maxiban® (36 grams per pound (g/lb) each of narasin and nicarbazin) and Flavomycin® (2, 4, or 10 g/lb of bambermycins activity) Type A medicated articles to make three-way combination Type C medicated feeds for use in broiler chickens. The combination Type C medicated feeds contain 27 to 45 g/ton narasin and 27 to 45 g/ton nicarbazin (in a fixed 1:1 ratio) and 1 to 2 g/ton bambermycins, and are used for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of March 8, 2001, and the regulations are amended in 21

CFR 558.95 and 558.363 to reflect the approval. The basis of approval is discussed in the freedom of information summary

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### **List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

#### **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

**§ 558.95 [Amended]**

2. Section 558.95 *Bambermycins* is amended in paragraph (d)(5)(iv) by adding “nicarbazin or” following “with”, and in paragraph (d)(5)(v) by removing “Nicarbazine” and adding in its place “Nicarbazin”.

3. Section 558.363 is amended by adding paragraph (d)(1)(xii) to read as follows:

**§ 558.363 Narasin.**

\* \* \* \*

(d) \* \* \*

(1) \* \* \*

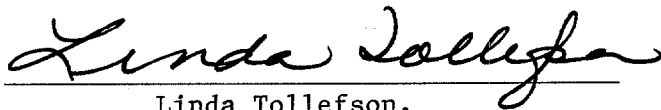
(xii) *Amount per ton.* Narasin, 27 to 45 grams; nicarbazin, 27 to 45 grams; and bambermycins, 1 to 2 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as the sole ration. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these animals has been fatal. Do not feed to laying hens. Withdraw 5 days before slaughter. Narasin and nicarbazin as provided by 000986, bambarmycins by 012799 in § 510.600(c) of this chapter.

\* \* \* \* \*

Dated: 4/23/2001  
April 23, 2001.



Linda Tollefson,  
Deputy Director,  
Center for Veterinary Medicine.

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL



[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S